CASE AUTH/3563/9/21 and CASE AUTH/3564/9/21

COMPLAINANT v BRISTOL-MYERS SQUIBB AND PFIZER

Concerns about the promotion of Eliquis (apixaban) on the Eliquis website

A contactable complainant who described him/herself as a health professional complained about the promotion of Eliquis (apixaban) on the Eliquis website where he/she selected the 'I am a HCP' tab on the landing page and went to the health professional section. The complainant was concerned with the messaging 'choose eliquis' at the top of every page and alleged that this bold statement should not be there. Each patient was individual and thus Eliquis might not be suited for that patient or they might not even be eligible and other competitor medicines might be better suited. In addition, the website did not include the necessary adverse event reporting wording.

The detailed response from Bristol-Myers Squibb and Pfizer is given below.

The Panel considered that the headline 'Choose Eliquis' might not necessarily be inappropriate. Clearly not every patient would be suitable for every medicine. Health professionals would use their professional judgement based on a number of factors and for certain patients it might be appropriate to choose Eliquis. The Panel did not consider that the complainant had established, on the balance of probabilities, that 'Choose Eliquis' as a headline banner on the promotional website in question was misleading or would not encourage the rational use of the medicine. The Panel therefore ruled no breaches of the 2021 Code.

The Panel noted the requirements of the Code that all promotional material must include the prominent adverse event reporting statement. The Panel noted that whilst the adverse event reporting statement which used wording in line with the Code appeared on the landing page, which was a gateway to both promotional and non-promotional websites, and whilst there was a link to the statement within the promotional website for health professionals, the statement was not included within the body of the promotional website and therefore the Panel ruled a breach of the 2021 Code in this regard.

The Panel did not consider that in relation to the allegations overall, the companies had failed to maintain high standards and therefore ruled no breach of the 2021 Code.

A contactable complainant who described him/herself as a health professional complained about the promotion of Eliquis (apixaban) on the Eliquis website.

COMPLAINT

The complainant stated that he/she was recently on the Eliquis website (Eliquis.co.uk) and selected the 'I am a HCP' tab on the landing page and went through the health professional section. The complainant was concerned with the messaging 'choose eliquis' at the top of every page and alleged that it was a bold statement that should not be there as it came across

as if the viewer was being told to choose the product over others for patients. Each patient was individual and thus Eliquis might not be suited for that patient or they might not even be eligible and other competitor medicines might be better suited. The complainant alleged breaches of Clauses 6 and 14. In addition, the website did not include the necessary adverse event reporting wording as per Clause 12.9 which stated: 'All promotional material must include the prominent statement "Adverse events should be reported. Reporting forms and information can be found at [website address which links directly to the MHRA Yellow Card site]. Adverse events should also be reported to [relevant pharmaceutical company]"'. The complainant alleged that high standards had not been maintained (Clause 5).

When writing to Bristol-Myers Squibb and Pfizer, the Authority asked it to consider the requirements of Clauses 5.1, 6.1, 12.9 and 14.4 of the Code.

RESPONSE

Both Bristol-Myers Squibb and Pfizer were involved in the development and review of the Eliquis UK website. However, as the website was certified by Bristol-Myers Squibb, Bristol-Myers Squibb responded on behalf of both companies (the Alliance).

Background

Eliquis.co.uk was developed by the Alliance, which aimed to provide up-to-date and relevant information on Eliquis to three different audience types. When an individual reached the landing page of eliquis.co.uk, they would see three clearly displayed and distinct sections – a section for health professionals, a section for patients who had been prescribed Eliquis and a section for members of the public. Further denoted by an asterisk on the health professional option, there was a statement directly below which described the purpose and intent of that section of the website. This read '*This promotional site is only intended for healthcare professionals seeking information on ELIQUIS (apixaban) in the UK'.

If the individual confirmed they were a health professional in the UK (by clicking on a button) and then selected to progress from the landing page, they would then reach a second pop-up box for a second self-declaration to confirm they were a health professional. Only after this second verification step, did they gain access to the Eliquis health professional homepage, and had the ability to navigate the website which had tailored information for this target audience.

Upon reading the complaint, the Alliance believed that the complainant was referring to the statement 'Choose Eliquis' which was located as a banner appearing at the top of multiple pages of the health professional section of the website. The screenshot provided by the PMCPA of the Eliquis.co.uk website showed a menu option 'Choosing Eliquis' and this particular part of the website did not include the 'Choose Eliquis' banner. On this basis, the Alliance responded in relation to the 'Choose Eliquis' banner, as shown in the enclosure.

The 'Choose Eliquis' banner was located at the top of the page. Embedded within the same banner and webpart, were six tabs, which included the Eliquis licensed indications. The tabs sat above the statement 'Choose Eliquis' and were static; they did not change regardless of which page the health professional navigated to. The health professionals could therefore access the licensed indications at all times above this statement, enabling them to choose the indication which was of interest or in which they practised. In light of this page layout, it was clear that the viewer would have the context of the appropriate indications in line with the

'Choose Eliquis' statement. Below the banner, the remainder of the page provided thorough, up-to-date, and detailed information, which was accurate, fair, balanced and within the licensed indications of Eliquis. This information further informed whether Eliquis was the appropriate treatment option for that health professional's patient type. On each of these webpages, in addition to the prescribing information (located at the very top of the page), a copy of the summary of product characteristics (SPC) and the patient information leaflet was readily available for further information on the appropriate use of Eliquis for eligible patients. The Alliance submitted that the information provided supported health professionals in making appropriate prescribing decisions, by providing them with accurate and complete information.

In light of the full range of information that had been provided on the page, the Alliance disagreed with the concern that the 'Choose Eliquis' banner gave the impression that the reader was being told to choose Eliquis over other products.

The Alliance submitted that the disclaimer at the outset, and on arrival at the landing page, very clearly described the purpose and the intent of the health professional section of the website – which was to provide promotional information on Eliquis for health professionals seeking information. The health professional would have reached the Eliquis site in the knowledge that it was a promotional website for Eliquis. The use of the phrase 'Choose Eliquis' implied that there was more than one treatment option, and the intention of the website was to provide evidence based and scientific information for the health professional to help make an informed decision on whether Eliquis could be the possible treatment for their patient. Furthermore, only UK health professionals were eligible to access this section of the website. The Alliance appreciated that this audience were skilled individuals educated in the management of patients and experienced in making informed patient decisions, and the Alliance did not believe that the statement 'Choose Eliquis' would deter the appropriate choice of treatment being selected for eligible patients which was aligned to the SPC recommendations. The Alliance therefore refuted a breach of Clauses 6.1 and 14.4.

The complainant highlighted concerns regarding an alleged omission of the necessary adverse event reporting wording. On reaching the landing page , the adverse event reporting statement could be found on that page directly below the three target audience categories. This information was displayed in full text and was clearly visible to provide easy access to the reader and did not need to be accessed via a link.

Once the health professional clicked through the health professional verification and had reached the homepage, the link to the prescribing information (PI) and adverse event reporting statement could be found immediately, in the top right-hand corner. The statement, 'For Prescribing and Adverse Event Reporting information, click here' was in bold, and the link itself was in purple to further add prominence. The health professional would see this link immediately on coming through the verification gateway, and it would be visible in the same view as the content when they landed on the page. This link to the adverse event information was built into the frame of the website, ensuring that it was always present, on every page that was viewed.

On clicking this link, the health professional could view the mandatory adverse event reporting statement. The adverse event statement appeared in a clear, prominent box, and in a larger font size than the prescribing information to comply with Clause 12.9. The complainant mentioned that the specific wording required by the Code was not included; the Alliance disagreed. The adverse event reporting text read 'Adverse events should be reported.

Reporting forms and information can be found via: United Kingdom - The yellow card scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. Adverse events should also be reported to Bristol-Myers Squibb via medical.information@bms.com or 0800 731 1736 (United Kingdom)'.

The Alliance disagreed that there had been a breach of Clause 12.9 due to the adverse event statement being accessible from every page of the promotional website.

Clause 5.1 High standards must be maintained at all times

The Alliance believed that it had acted responsibly in providing accurate and detailed information to enable health professionals to make appropriate prescribing decisions based on the eligibility of their patients. The Alliance believed it was important to consider the audience type when communicating and believed that the information that had been provided was appropriate and conferred respect and trust in the audience. The Alliance ensured that the mandatory adverse event reporting information had been provided and was easily accessible regardless of where the health professional navigated to on the website and was in line with the Code's expectations. Considering the above, the Alliance strongly refuted a breach of Clause 5.1.

The Alliance stated that it was committed to following the Code and took its responsibility to uphold the high standards very seriously.

PANEL RULING

The Panel considered that the banner headline 'Choose Eliquis' on the promotional website for health professionals might not necessarily be inappropriate. Clearly not every patient would be suitable for every medicine. Health professionals would use their professional judgement in deciding which treatment to give a patient based on a number of factors and for certain patients it might be appropriate to choose Eliquis. The Panel did not consider that the complainant had established, on the balance of probabilities, that 'Choose Eliquis' as a headline banner on the promotional website in question was misleading or would not encourage the rational use of the medicine. The Panel therefore ruled no breach of Clauses 6.1 and 14.4 of the 2021 Code.

The Panel noted that the adverse event reporting statement appeared on the landing page which provided links to websites aimed at each of the three target audiences listed: health professionals, patients on apixaban and members of the public. The wording used was in line with the requirements of the Code. When reaching the website aimed at promoting to health professionals each page stated in the top right-hand corner 'For Prescribing and Adverse Event reporting information, click here' which appeared to be an active link. The Panel, however, did not have the linked information before it. Nonetheless, the Panel noted the requirements of Clause 12.9 which stated that all promotional material must include the prominent adverse event reporting statement. The Panel noted that whilst the adverse event reporting statement appeared on the landing page, which was a gateway to both promotional and non-promotional websites, and whilst there was a link to the statement within the promotional website for health professionals, the statement was not included within the body of the promotional website and therefore the Panel ruled a breach of Clause 12.9 of the 2021 Code in this regard.

The Panel did not consider that in relation to the allegations overall, the companies had failed to maintain high standards and therefore ruled no breach of Clause 5.1 of the 2021 Code.

Complaint received	**29 September 2021**
Case completed	**26 April 2022**